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| 09/904,179 | 07/11/2001 | Dan K. Ahlgren | 5510US | 1180 |
| 30328 | 7590 | 12/31/2003 | EXAMINER | |
| NU VASIVE, INC. 10065 OLD GROVE ROAD SAN DIEGO, CA 92131 | | | RAMANA, ANURADHA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3732 | |

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,179

Applicant(s)

AHLGREN, DAN K. *cd*

Examiner

Anu Ramana

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 18 and 19 is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 9-17, 20-27 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 6 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/11/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 11, 14, 16, 17, 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Brantigan (US 5,192,327).

Regarding claims 1, 5, 11, 14, 16, 17, 23, 24, 26 and 27, Brantigan discloses an intervertebral support system 10 with a center portion having top and bottom recesses facing cranially and caudally, a top portion having bottom recesses facing caudally, and a bottom portion having top recesses facing cranially wherein the top and bottom portions are interchangeable and each of the top, center and bottom portions is made of metal (Figures 4 and 14, col. 4, lines 1-19, col. 5, lines 30-34 and col. 7, lines 1-3)

The method steps of claims 17, 23 and 24 are inherently performed during assembly and insertion of the Brantigan intervertebral support system between adjacent vertebrae.

Claims 1, 4, 9-11, 17 and 24-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Cohen et al. (US 6,454,806).

Regarding claims 1, 4, 9-11, 17 and 24-26, Cohen et al. disclose an implant or prosthesis or intervertebral support system 1B having a center portion 44 having top and bottom recesses facing cranially and caudally, a top portion 2B having recesses facing caudally, and a bottom portion 3B having recesses facing cranially (Figure 6, col. 1, lines 4-8, col. 8, lines 62-67 and col. 9, lines 1-9).

The method steps of claims 17, 24 and 25 are inherently performed during assembly and insertion of implant 1B between adjacent vertebrae.

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Regarding claim 27, Cohen et al. disclose an embodiment (1A) of the implant having a top portion 2A with a bottom recess and a bottom portion 3A with a top recess such that the two portions interlock with each other.

The method steps of claim 27 are inherently performed during assembly and insertion of implant 1A between adjacent vertebrae.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. in view of Nicholson et al.

Cohen et al. do not disclose that implant 1B is made from bone allograft.

Nicholson et al. teach that bone allograft material can be used to fabricate implants to match the elastic properties of a patient's bone (col. 4, lines 9-13).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized bone allograft as taught by Nicholson et al. for the purpose of fabricating device 1B of Cohen et al. to match the elastic properties of a patient's bone.

Claims 12, 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al.

Regarding claims 12 and 13, it would have been an obvious matter of design choice to have dimensioned implant 1B with a size less than 6 mm or a size less than 8 mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose, 105 USPQ 237 (CCPA 1955).*

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Regarding claim 16, Cohen et al. disclose that implant 1B is made of a biocompatible material (col. 3, line 54). Although Cohen et al. do not disclose that implant 1B is made of metal would have been obvious to one having ordinary skill in the art at the time the invention was made to have made implant 1B of metal, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 20, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. in view of Yoakum et al. (US 5,484,403).

Cohen et al. do not disclose a surgical cannula for insertion of implant 1B.

Yoakum et al. teach the use of a cannula 9 with a plunger 3 for implanting a cylindrical object 11 into a body (col. 1, lines 7-9, lines 56-67, col. 2, lines 1-9 and lines 25-43).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized a cannula, as taught by Yoakum et al., for deposition of cylindrical implant 1B.

Regarding claims 21 and 22, it would have been an obvious matter of design choice to have utilized a cannula having an interior diameter not exceeding 6 mm or 8 mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

The method steps of claims 20-22 are rendered obvious by the combination of Cohen et al. and Yoakum et al.

Response to Arguments

Applicant's arguments with respect to claims 1, 4, 5, 9-17 and 20-27 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 8, 18 and 19 are allowed.

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Claims 2, 3, 6 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR *Anuadha Ramana*

December 27, 2003

Pedro Philogene
PEDRO PHILOGENE
PRIMARY EXAMINER